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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,953	06/22/2001	Varouj Amirkhanian	1031/205	7677

26588 7590 07/12/2004

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EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 07/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/887,953	AMIRKHANIAN, VAROUJ	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *19 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

The amendment filed May 5, 2004 is acknowledged and has been entered. NOTE: The listing of claims filed May 5, 2004 shows that claim 21 has been withdrawn. However, the claim was rejected in a previous office action and is rejected in this office action (see below). It is unclear if this was a typo or if Applicant intended to cancel claim 21. Therefore, Examiner has addressed claim 21 as if it were still part of the rejected claims.

Information Disclosure Statement

The Sepaniak et al., reference entitled "Demonstration of an Integrated Capillary Electrophoresis-laser induced fluorescence fiber-optic sensor" has not been considered because the copy received by the USPTO contains the pages of every other sheet (i.e. 1889, 1891, 1893, 1895, 18971899 and 1891), the even numbered pages are missing. Therefore, the complete relevance of the reference cannot be determined. It is recommended by Examiner to resubmit the Sepaniak et al reference for reconsideration.

NOTE: In the Response received May 5, 2004 under the section entitled REMARKS; the Applicant states that a full copy of the Sepaniak reference is enclosed. However, the Examiner has not received this reference and therefore, the Sepaniak et al reference has not been considered. In the event, the Applicant sends the full copy of the Sepaniak reference, the Applicant is also required to resubmitted an IDS listing this reference.

Specification

The amendment filed My 5, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: On page 16, line 18 to page 17, line 5 of the specification. The disclosure (i.e., as shown in Fig 2B, a transition in width from the width of the separation channel 504 to the width of the collar 10). The applicant has not defined the term transition and from the figures has not clearly disclosed where a transition would begin and end.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicant discloses that the zone for optical detection of sample components is located at a widened zone along the separation channel. And that the widened detection zone is a micro-bore collar having a micro-channel that coaxially surrounds the exit of a capillary column that defines a

capillary channel (page 7, lines 3-8 and page 12, line 23 – page 13, lines2). On pages 16, line 18 – page 17, line 5 in the specification. The applicant discloses that as the analytes flow from the separation channel 504 of capillary column 22 into the collar 10, the analytes remain subject to the applied potential. As a result, the analytes continue to maintain separation state as they migrate/flow past the detection zone 20. Some mixing or diffusion of the analytes may occur in the collar near the exit of the separation channel 504, but analytes "regroup" into separated state as they continue down along the collar 10 towards the detection zone 20. The detection zone 20 is preferably located at 100 x 500 ID of the collar, more like 225 times ID, to provide sufficient distance for the analytes to regroup before detection at the detection channel 504, the analyte bands are narrower in the axial direction. Thus the detection resolution may be improved as a result. The only specific disclosure of a transition occurs on page 1, lines 20-21 in the specification which discloses that bioanalysis, such as DNA analysis, is rapidly making the transition from a purely scientific quest for accuracy to a routine procedure with increased, proven dependability. The applicant does not disclose a transition in width from the first width of the separation channel to the second width of the detection section. There is no description in the specification disclosing a transition from the first width of the separation channel to the second width of the detection section.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-18 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 5 "a transition" is vague and indefinite. It is unclear what applicant is referring to. There is no definition provided for the term in the specification. See also deficiencies found in claim 16, part (a).

Claim 1 is vague and indefinite because it is unclear where the first width of the separation channel is located. Is it located at the exit or entrance? And if it is the exit, at what point of the exit, the inside of the separation channel or the outside of the separation channel (see Fig. 2B)? And at what point inside or outside does the transition precisely occur?

Claim 21, lines 4 & 5 "having a second width larger than the first width" is vague and indefinite. It is unclear if "the first width" is referring to the first width of the separation channel or if it is referring to a first width of the detection section. It is unclear if the detection section has a second width larger than a first width of the detection section or if the width of the detection section is larger than the width of the separation channel.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 2, 10 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu et al (US 5,763,277).

Zhu et al disclose a detection system which comprises a capillary tube (col 6, line 46) used for electrophoresis (separation channel) (col 2, lines 49-51). Zhu et al disclose that sample analyte fluorescence is caused to occur by the application of energy (excitation radiation) to sample analytes caused to be present within the system (col 2, lines 62-65, see also figure 1). Zhu et al disclose the use of an axially oriented fiber optic which is directed into an end of the detection section in proximity to the detection zone. Zhu et al disclose that this fiber optic transmits the produced fluorescence (radiation emission) to a detector system (col 3 lines 1-6, see also figure 1). Zhu et al also disclose that the inner diameter of the axially oriented system component is increased at the location of contained axially oriented fiber optic means (col 5, lines 1-3).

With respect to a transition as recited in the instant claims Zhu et al disclose an exit from a small diameter (first width) to a larger diameter (second width) (see figure 3). Therefore, Zhu et al disclose a transition from a first width to the second width.

With respect to the detection section defining a detection zone at a distance of 100 to 500 times the second width from the transition as recited in the instant claims, the optimum distance of the second width from the transition can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

8. Claims 1, 2, 10 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yin et al (US 5,650,846).

Yin et al disclose a microcolumnar separation device (col 4, lines 20-67). Yin et al disclose that this microcolumn separation device can be a capillary electrophoresis channel (separation channel) (col 4). Yin et al disclose a means for introducing excitation radiation to the sample. Yin et al disclose a fiber optic for axially detection radiation emission (col 2, lines 38-40). Yin et al disclose that the separation channel has a first width and a transition from a first width to a second width (see Fig. 8).

With respect to the detection section defining a detection zone at a distance of 100 to 500 times the second width from the transition as recited in the instant claims, Yin et al is silent

with respect to the distance. However the optimum distance of the second width from the transition can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

9. Claims 3, 4, and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yin et al in view of Taylor et al (Axial-beam Laser-Excited Fluorescence Detection in Capillary Electrophoresis, Anal. Chem. 1992, vol. 64, 1741-1744).

See above for teachings of Yin et al.

Yin et al differ from the instant invention in failing to teach a means for introducing excitation radiation axially at the detection zone. Zhu et al also fails to teach a boundary material that surrounds the light emitting material for guiding the excitation radiation from the excitation source to the detection zone.

Taylor et al disclose the use of an optical fiber, which focuses the excitation laser beam, which directs the light along the capillary rather than across it. Taylor et al

also disclose that this fiber is inserted into the separation capillary (col 1, page 1742, lines 6-10). The use of this optical fiber allows for axial-beam fluorescence excitation which provides the added advantage of very little scattered light originating from the capillary walls which allows the use of capillaries with intact polyamide coatings without problems of interference due to absorption or greatly increased fluorescence background. It also provides for a longer absorption path length compared to irradiation across the capillary (col 1, page 1741, lines 35-47). Taylor et al also disclose the use cladding material and a jacket, which surround the fiber for guiding the excitation radiation from the excitation source to the detection zone.

It would have been obvious to one of ordinary skill in the art to incorporate the use of a fiber and a surrounding material as taught by Taylor et al into the detection system of Yin et al because Taylor et al shows that the use of this fiber and surrounding material allows for axial-beam fluorescence excitation which provides the added advantage of very little scattered light originating from the capillary walls which allows for the use of capillaries with intact polyamide coatings without problems of interference due to absorption or greatly increased fluorescence background. It also provides for a longer absorption path length compared to irradiation across the capillary.

With respect to the light transmitting material having a refractive index greater than the refractive index of the boundary material as recited in the instant claims. It would have been obvious to one or ordinary skill in the art to incorporate a light transmitting material which has a refractive index greater than the refractive index of the

boundary material because this would allow one to maintain the light with the fiber optic so that lose of the intensity of the light would not occur.

10. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yin et al in view of Taylor et al as applied to claims 1, 2, 10 and 15-18 above, and further in view of Letcher et al (US 6,326,213) or Liu et al (US 5,444,807).

See above for teachings of Yin et al and Taylor et al.

Yin et al and Taylor et al differ from the instant invention in failing to teach the means for axially detecting radiation emission shares the same single fiber as the means for introducing excitation radiation axially to transmit excitation radiation and radiation emission.

Letcher et al disclose a single step-tapered fiber used for excitation and detection (col 3, lines 1 and 2, see also abstract). The use of this fiber allows for enhancement of the sensitivity of a fiber-optic biosensor using fluorescent immunoassay techniques for the rapid detection of an analyte.

Liu et al (US 5,444,807) disclose a single fiber optic for both axial light input to and output from flow through detectors (abstract and col 6, lines 44-60). Liu et al disclose that this provides for a novel technique by which light absorption and fluorescence may be used as measures of properties of small amounts of a flowing fluid analyte, particularly in conjunction with liquid chromatography and capillary electrophoresis (col 4, lines 36-50).

It would have been obvious to one of ordinary skill in the art to incorporate the fiber of Letcher et al into the modified system of Yin et al because Letcher et al shows

that the use of this fiber allows for enhancement of the sensitivity of a fiber-optic biosensor using fluorescent immunoassay techniques for the rapid detection of an analyte.

It also would have been obvious to one of ordinary skill in the art to incorporate the fiber optic of Liu et al into the modified system of Yin et al because Liu et al shows that this provides for a novel technique by which light absorption and fluorescence may be used as measures of properties of small amounts of a flowing fluid analyte, particularly in conjunction with liquid chromatography and capillary electrophoresis.

11. Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yin et al in view of Taylor et al and Letcher et al or Liu et al as applied to claims 1, 2, 5, 10 and 15-18 above, and further in view of Hazman et al (US 5,625,403).

See above for teachings of Yin et al, Taylor et al, Letcher et al and Liu et al.

Yin et al, Taylor et al, Letcher et al and Liu et al differ from the instant invention in failing to disclose a confocal optical element that transmits excitation radiation and radiation emission.

Hazman et al disclose the use of a dichroic beam combiner along with a set of lens. This dichroic beam combiner is used to selectively reflect and transmit light according to its wavelength (col 4, lines 30-33). The use of the beam combiner and set of lens allows for the combination of laser beams and enabling the realization of a practical high power optical head.

It would have been obvious to one or ordinary skill in the art to incorporate the beam combiner and set of lens as taught by Hazman et al into the system of Yin et al

because Hazman et al shows that the use of the beam combiner allows for selectivity of light reflection and transmission according to its wavelength and the beam combiner and set of lens also allows for the combination of laser beams and enabling the realization of a practical high power optical head.

12. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al (Axial-Beam Laser-Excited Fluorescence Detection in Capillary electrophoresis, Anal. Chem. 1992, Vol. 64, 1741-1744) in view of Yin et al (US 5,650,846) or Zhu et al (Us 5,763,277).

Taylor et al disclose a detection system for axial-beam laser excited fluorescence detection in capillary electrophoresis. Taylor et al disclose the use of a fiber optic which focuses the excitation laser beam which directs the light along the capillary rather than across it (col 1, page 1741, lines 1-27). Taylor et al also disclose that this fiber is directed into an end of the detection section in proximity to the detection zone (col 1, page 1742, lines 8-10). Taylor et al also disclose the use of cladding material and a jacket which surround the fiber for guiding the excitation radiation from the excitation source to the detection zone (col 2, page 1741, lines 12-18). Taylor et al also disclose a means for detecting radiation emission from the detection zone (col 1, page 1742, lines 22-39).

Taylor et al differs from the instant invention in failing to teach the separation channel having a first width, and the detection zone having a second width larger than the first width.

Yin et al disclose a microcolumnar separation device (col 4, lines 20-67). Yin et al disclose that this microcolumn separation device can be a capillary electrophoresis channel (separation channel) (col 4). Yin et al disclose that the separation channel comprises a detection section (Fig. 8, items 18, 124 139, 130 and 128, the detection region extends from item 18 to item 130). Yin et al disclose that the separation channel comprises a flare located at the end of the separation channel (col 7, line 48 – column 8, line 9). Yin et al disclose that detection section has an enlarged opening to the lumen of the separation channel for receiving the optical fiber and for a zone of detection. Yin et al disclose that detection zone provides the alignment and nonfixed confinement of optical fiber to the separation channel.

Zhu et al disclose a detection system which comprises a capillary tube (col 6, line 46) used for electrophoresis (separation channel) (col 2, lines 49-51) which defines a detection zone. Zhu et al also disclose that the inner diameter of the axially oriented system component is increased at the location of contained axially oriented fiber optic means (col 5, lines 1-3). Zhu et al disclose that the increased diameter provides a non-constricted annular space in which sample analyte containing sample solution can flow, in the presence of the fiber optic (col 6, lines 15-21).

It would have been obvious to one of ordinary skill in the art to incorporate a detection zone as taught by Yin et al into the device of Taylor et al because Yin et al shows that this detection zone provides the alignment and nonfixed confinement of optical fiber to the microcolumn.

It also would have been obvious to one of ordinary skill in the art to incorporate a separation channel and detection zone has taught by Zhu et al into the device of Taylor et al because Zhu et al shows that this separation channel and detection zone provides a non-constricted annular space in which sample analyte containing sample solution can flow, in the presence of the fiber optic.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 are rejected under the judicially created doctrine of double patenting over claims 1-19 of U. S. Patent No. 6,529,275 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: Both the instant application and US Patent 6,529,275 claim a detection system for a bio-separation device a detection section along the separation channel having a second width larger than a first width and a

transition from the first width to the second width, the detection section defining a detection zone at a distance of 100 to 500 times the second width from the transition; means for introducing excitation and means for axially detecting radiation emission.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim 21 is provisionally rejected under the judicially created doctrine of double patenting over claims 1-31 of copending Application No. 09/887,871. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: a detection system comprising a detection section along the separation channel defining a detection zone, the separation channel having a first width, and the detection zone having a second width larger than the first width; means for introducing excitation radiation axially and means for detecting radiation emission from the detection zone.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other

copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Response to Arguments

13. Applicant's arguments filed May 5, 2004 have been fully considered but they are not persuasive.

112 Rejection Arguments

Applicant argues that amended claims 1 and 16 clarify the reference to "second width" and Applicant further argues that the amended specification refers to the exit of the separation channel 504 into the collar 10 as a transition in width from the width of the separation channel 504 to the width of the collar 10 and such amendment does not introduce new matter as supported by Figure 2B. This is not found persuasive because Figure 2B does not clearly define a transition. For example, where is the transition occurring at the exit of the separation channel? The exact point of exit, just outside the exit, the inner point of the exit of the capillary column, the outer point of exit of the capillary column? The applicant has not clearly defined a transition and therefore the amendment introduces new matter.

Applicant further argues that related patent application serial no. 09/887,872 had issued as U.S. Patent No. 6,529,275, which claims also employ this "transition" recitation based on essentially a similar disclosure with respect to this structure. And that while individual applications should be reviewed and examined on its own merits with respect to prior art, to fine the use of similar recitation of "transition" in the present application to be unsupported by the original specification would be inconsistent and

arbitrary discretion of the Examiners. This is not found persuasive because Examiner is relying on the original disclosure of the current application being reviewed. The Examiner is not relying on a similar disclosure or any other disclosure. The current application does not clearly define "a transition" and therefore the amendment to the claims and the specification is considered new matter and thus the rejection is maintained.

103 Rejection Arguments

14. Applicant argues that Zhu does not teach or suggest that the detection zone could or should be located at a distance 100 to 500 times of the width of the wider detection section, from the transition from the narrower separation channel. Applicant argues that Zhu is silent to the location of the detection zone and to defining the detection zone to be 100 to 500 times the second width of the detection section from the transition. Examiner agrees that Zhu does not specifically define the detection zone and that the detection zone be located at a distance 100-500 times second width of the detection section from the transition. However, Zhu et al does teach the concept that the fiber optic is positioned in a widened section of the separation channel and that the fiber optic is placed at a distance from the transition point and as stated in the previous office action and above, the optimum distance can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it is unclear in the instantly recited claims where the first width of the separation channel is located and is also unclear what applicant means by transition (see 112 2nd rejections above). Applicant further argues that Zhu did not address the concern with

mixing, diffusion and regrouping of analyte back into separated state and that Zhu would not have disclosed the specific location of the detection zone to be significantly downstream of the transition, without consideration of mixing diffusion and regrouping of analytes and that the location of the detection zone at the specific recited distance would not be an obvious matter of routine experimentation or design choice, since the motivation for such issues as analyte mixing, diffusion and regrouping is not found anywhere in Zhu. In response to applicant's argument that the references fail to address certain concerns of applicant's invention, it is noted that the features upon which applicant relies (i.e., mixing, diffusion and regrouping of analyte back into separated state) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that Zhu teaches away from the present invention as claimed. Applicant states that Zhu does not even need to address the issues of analyte mixing, diffusion and regrouping by simply placing the end of the optical fiber within 1 time of the increased 1d from the transition form the smaller diameter and that by having the detection fiber end close to the transition, there would be significantly less opportunity for analyte mixing and diffusion, and hence regrouping at a significant distance from the transition is not needed. This is not found persuasive because as stated above the instantly recited claims do not require analyte mixing and diffusion and regrouping and further, it is unclear in the instantly recited claims where the first width of the separation channel is located and it is also unclear what applicant means by transition. Therefore,

it is the Examiner position that it would have been obvious to one of ordinary skill in the art to optimize the distance of the detection section from the transition.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

15. Applicant argues that in the Yin et al reference there would be significant analyte diffusion and mixing with the flushing fluid throughout the downstream flushing flow. And regrouping of mixed or diffused analytes is not possible and hence not contemplated in view of the flushing fluid. Applicant states that Yin is only concerned with maintaining the end of the fiber in close proximity to the flared end of the capillary column to detect analytes before such mixing and diffusion occur in the flushing flow and that Yin et al is not concerned with and does not need to be concerned with regrouping of analyte mixing and diffusion. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., mixing, diffusion and regrouping of analyte) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, it is unclear

in the instantly recited claims where the transition begins and therefore it is unclear how to precisely determine where the distance of 100 to 500 times the second width of the detection section from the transition. Therefore, it is the Examiner position that the Yin et al rejection reads on the instantly recited claims and the obviousness rejection concerning the optimum distance is proper.

Applicant states that the other arguments presented in connection with Zhu but not specifically mentioned here are equally applicable to Yin. Therefore, the rejections by the Examiner presented in connection with Zhu are equally applicable to Yin.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary W. Counts
Examiner
Art unit 1641
June 28, 2004

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SUPERVISORY PATENT EXAMINER
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07/07/04